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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,532	07/15/2003	Pradip Mukerji	7097.US.01	7501

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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,532	MUKERJI ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 and 2 drawn particularly to, and claims 5-9 and 12-16 each drawn in part to, a first polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFA polyketide synthase [PKS] set forth in SEQ ID NO:10, or variants thereof, to expression vectors and recombinant host cells comprising same, and to a method of use thereof in making the encoded PKS utilizing same, classified, *inter alia*, in class 536, subclass 23.2.

2. Claims 3 and 4, drawn particularly to, and claims 5-9 and 12-16 each drawn in part to, a second polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFB polyketide synthase [PKS] set forth in SEQ ID NO:11, or variants thereof, to expression vectors and recombinant host cells comprising same, and to a method of use thereof in making the encoded PKS utilizing same, classified, *inter alia*, in class 536, subclass 23.2.

3. Claims 10 and 11, each drawn in part to a first polypeptide comprising the amino acid sequence of the *T. aureum* ORFA PKS set forth in SEQ ID NO:10, or variants thereof, classified in class 435, subclass 183.

4. Claims 10 and 11, each drawn in part to a second polypeptide comprising the amino acid sequence of the *T. aureum* ORFB PKS set forth in SEQ ID NO:11, or variants thereof, classified in class 435, subclass 183.

5. Claims 17, 18, or 20, each drawn in part to a first transgenic plant that comprises a polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFA PKS set forth in SEQ ID NO:10, or variants thereof, classified in class 800, subclass 295.

6. Claims 17, 18, or 20, each drawn in part to a second transgenic plant that comprises a polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFB PKS set forth in SEQ ID NO:11, or variants thereof, classified in class 800, subclass 295.

7. Claim 19, 24 and 25, drawn to compositions comprising either of at least two species of oils, i.e., either eicosapentaenoic acid [EPA] or docosahexaenoic acid [DHA], classified in class 554, subclass 1.
8. Claims 21-23, drawn in part to an alternate method of use of the first polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFA PKS set forth in SEQ ID NO:10, or variants thereof, in producing a polyunsaturated fatty acid in a transformed host cell, classified in class 435, subclass 41.
9. Claims 21-23, drawn in part to an alternate method of use of the second polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFB PKS set forth in SEQ ID NO:11, or variants thereof, in producing a polyunsaturated fatty acid in a transformed host cell, classified in class 435, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group 1 and Group 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical entities having significantly different coding capacities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different functions and different effects.

Inventions of Group 1 and Group 3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical entities of different chemical classes requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

Inventions of Group 2 and Group 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical entities of different chemical classes requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

The invention of Group 1 is unrelated to the inventions of Groups 4-7 and 9. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical and/or physiological entities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

The invention of Group 2 is unrelated to the inventions of Groups 5-8. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical and/or physiological entities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

Inventions of Group 1 and Group 8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group 1 can be used in a different method such as the method of making a polyunsaturated fatty acid of Group 8.

Inventions of Group 2 and Group 9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group 2 can be used in a different method such as the method of making a polyunsaturated fatty acid of Group 9.

Inventions of Group 3 and Group 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical entities having significantly different primary structures requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different functions and different effects.

The invention of Group 3 is unrelated to the inventions of Groups 5-9. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical and/or physiological entities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

The invention of Group 4 is unrelated to the inventions of Groups 5-9. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical and/or physiological entities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

Inventions of Group 5 and Group 6 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent, multicellular, physiological entities that do not require, as claimed, common transgenic material and that separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different effects.

The invention of Group 5 is unrelated to inventions of Groups 7-9. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01. In the instant case the different inventions are independent chemical and/or physiological entities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

The invention of Group 6 is unrelated to inventions of Groups 7-9. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01. In the instant case the different inventions are independent

chemical and/or physiological entities requiring separate searches in the patent and non-patent literature, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

Inventions of Group 2 and Group 9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group 2 can be used in a different method such as the method of making a polyunsaturated fatty acid of Group 9.

Inventions of Group 7 and Group 8 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as extraction from animal tissue.

Inventions of Group 7 and Group 9 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as extraction from animal tissue.

The inventions of Group 8 and 9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions are independent chemical entities that are not required, as claimed, to have a common, heterologous, polynucleotide, are not disclosed to be used together, and have different modes of operation, different functions, and different effects.

Because these inventions are distinct for the reasons given above and/or have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

A telephone call was made to Ms. Cheryl L. Becker on 3 February 2006 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must

include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
3 February 2006

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER